



VIA FEDERAL EXPRESS

WARNING LETTER

FLA-01-46

March 20, 2001

David L. Trujillo, President
3D of Key West, Inc.
660 Shrimp Road
Stock Island, Florida 33040

Dear Mr. Trujillo:

We inspected your firm at the above address on December 20, 2000, and found that you have a serious deviation from the Seafood HACCP regulations (21 CFR Part 123). This deviation, which was previously brought to your attention, causes your cooked stone crab claws to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviation was as follows:

You must have a written HACCP plan that lists the food safety hazards that are reasonably likely to occur to comply with 21 CFR 123.6(c)(1). However, your firm's HACCP plan for cooked stone crab claws does not list the food safety hazard of Pathogen Growth and Toxin Formation.

Note: This hazard is reasonably likely to occur at the pre-grading and pre-shipment refrigerated storage steps in your process. Each of these steps should be identified as a critical control point in your HACCP plan.

We may take further action if you do not promptly correct this violation. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct this deviation. You may wish to include in your response documentation such as a revised HACCP plan and revised monitoring records or other useful information that

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would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when you will correct the deviation.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Kendall W. Hester, Compliance Officer, 555 Winderley Place, Ste. 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Mr. Hester at (407) 475-4730.

Sincerely,

A handwritten signature in black ink that reads "David J. Hallant". The signature is written in a cursive style with a large initial "D".

for

Emma R. Singleton
Director, Florida District